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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------------------|---------------------|------------------|
| 09/850,363 | 05/07/2001 | Michael Franciscus W. C. Martens | 294-100 | 2538 |

23869 7590 03/08/2004

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| EXAMINER |
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COUNTS, GARY W

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| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/850,363

Applicant(s)

MARTENS ET AL.

Examiner

Gary W. Counts

Art Unit

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 26 January 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 19-28.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

DETAILED ACTION

Attachment to Advisory Action

Continuation of 5 NOTE: because: Applicant argues that Nakanome et al. disclose an assay, for measuring pro-insulin and that Nakanome et al state that their assay is specific for proinsulin, and failed to detect both insulin and C-peptide. This is not found persuasive because as stated in the previous office action the recitation "a real-time insulin test system" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Therefore, the claim merely requires a reservoir comprising monoclonal anti-C peptide antibodies coated to the reservoir (limitations taught by Nakanome et al., See previous office action for teachings of Nakanome et al). Applicant further argues that Nakanome requires a lengthy incubation period. This is not found persuasive because of reasons stated above concerning the recitation "real time" in the preamble of the claim.

Applicant argues that Landa et al. merely disclose a fluorescence analyzer and that nowhere in Landa et al. is there any disclosure or suggestion of a real-time assay to measure insulin levels using monoclonal anti-insulin or anti-C peptide antibodies useful

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as a tracer in the reservoir. This is not found persuasive because Examiner has not relied upon Landa et al for teachings these limitations. As discussed above, Nakanome teaches these limitations. Examiner has relied upon Landa et al for teaching the advantages of a photomultiplier detector for fluorescence immunoassay. Furthermore, Nakanome et al specifically teaches a spectroscopic measurement device. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the photomultiplier detector such as taught by Landa et al for the fluorescence analyzer of Nakanome et al because Landa et al shows that the use of this photomultiplier detector provides for rapid and sensitive analysis and is practical in the clinical environment.

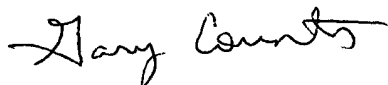
Applicant argues that Milford et al fails to provide any disclosure or suggestion that antibodies are present in dried form in a reaction reservoir. This is not found persuasive because Examiner has not relied upon Milford for teaching the antibody in the reservoir. As stated in the previous office action Nakanome et al teaches the labeled antibody in the reservoir. Examiner has relied upon Milford et al for the teaching that it is known in the art to lyophilize antibodies and that this lyophilization provides the advantage of stabilizing antibodies. Therefore, it is the Examiner's position that the combination of Nakanome et al., Landa et al., and Milford et al is proper and reads on the instantly rejected claims

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

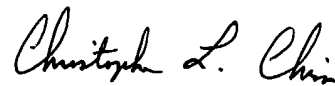
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary W. Counts
Examiner
Art Unit 1641
February 26, 2004



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641